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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,407	01/08/2002	Satoshi Asai	7005-129-999	8994

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PENNIE & EDMONDS
1155 Avenue of The Americas
New York, NY 10036-2711

EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,407

Applicant(s)

ASAI ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 4-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - (a) The use of the trademark "GeneChip" at paragraphs 0035, 0065, 0143, 0144, 0150, 0153, 0160 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is necessary.

Claim Objections

2. Claims 4, 5, 6, 7, 8, 9 and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4, 5, 6, 7, 8, 9 and 10 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al (Journal of Histochemistry and Cytochemistry, Vol. 40, No. 4, pages 591, 1992, Abstract). Applicant has claimed a method of screening genes which comprises performing *in situ* hybridization of a tissue or cell sample of an organism, using a probe which hybridizes specifically with mRNA an/or an expression sequence tag being a product of gene expression, and examining the localization of the mRNA and/or expression sequence tag in the tissue or cell.

Nagata et al teach a method of screening a gene comprising performing *in situ* hybridization of a tissue sample using a probe which hybridizes specifically with mRNA and examining the localization of the mRNA in the tissue (see entire abstract).

Regarding claim 2, Nagata et al teach the embodiment of claim 1, wherein the mRNA is expressed in tissue (abstract). Therefore, Nagata et al. meet all of the limitations of claims 1 and 2 of the instant invention.

5. Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Coghlan et al. (US 5,497,692, January 28, 1997). Regarding claim 1, Coghlan et al teach a screening method comprising performing *in situ* hybridization of a tissue sample using a probe which hybridizes specifically with mRNA and examining the localization of the mRNA in the tissue (see abstract and col. 1, lines 9-19 and col. 14, line 56 to col. 15, line 3).

Regarding claim 2, Coghlan et al. teach a method according to claim 1, wherein the mRNA is expressed in a tissue (col. 1, lines 9-19 and col. 14, line 56 to col. 15, line 3). Therefore, Coghlan et al. meets all of the limitations of claims 1 and 2 of the instant invention.

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6. Claims 1, 2, 11 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Toran-Allerand (US 5,990,078, November 23, 1999). Regarding claim 1, 2, 11, Toran-Allerand teach a method of monitoring gene expression which comprises collecting cell sample from a organism each before occurrence, and after occurrence of an event, performing in situ hybridization in respect of each sample using a probe that specifically hybridizes with mRNA and examining changes in localization of the cell (col. 13, lines 24-65).

Regarding claim 12, Toran-Allerand teaches the embodiment of claim 1, wherein a cell sample is collected from an organism at least two different points in time after occurrence of an event (col.13, lines 24-65 and col. lines 13-17; see also col. 3, lines line 56 to col. 4, lines 31). Therefore, Toran-Allerand meets the limitations of claims 1, 2, 11 and 12 of the instant invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Joly et al (US 6,342,495 B1, filing date December 15, 1999). Regarding claims 1 and 3, Joly et al teach a method of screening comprising performing in situ hybridization of a tissue sample of an organism using a probe which hybridizes specifically with mRNA and examining the

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localization of the mRNA. The reference further teaches wherein the mRNA is confirmed with a DNA microarray (col. 20, lines 41-67 and col. 21, line 1-3). Therefore, Joly et al meet the limitations of claims 1 and 3 of the instant invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ness et al. (US 6, 027, 890, February 22, 2000). Regarding claim 3, Ness et al. disclose techniques that are useful for detecting the expression of a gene or its mRNA in a large pool of unrelated DNA and RNA molecules. Ness teaches that these techniques may be use along or in conjunction with one another to investigate the structure or expression of a gene or its mRNA in unknown pool of nucleic acids. Ness et al disclose that *in situ* hybridization is one technique that allows the precise location of a given mRNA in a specific population of cells within a tissue by using a

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probe which hybridizes specifically with the mRNA (col. 42, lines 33-53, col. 49, line 60 to col. 50, line 5). Ness et al further disclose that DNA array technology or microarray technology is another technique which can be utilized in the identification of individual clones and to quantitatively measure the relative of expression of genes in two different RNA samples. (col. 54, lines 5-47, especially lines 30-47). Therefore, in view of the teachings of Ness et al, it would obvious to one of ordinary skill in the art at the time of the claimed invention that the techniques in situ hybridization followed by DNA microarray analysis or visa versa could be utilized to investigate mRNA expression and localization with a reasonable expectation of success.

Prior Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schena et al. (Science, Vol. 270, pages 467-470, October 20, 1995) teach quantitative monitoring of gene expression via hybridization with a complementary DNA microarray.

Conclusion

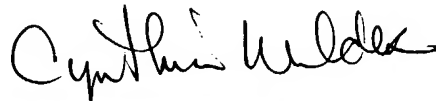
13. No claims are allowed. Claims 1, 2, 3, 11 and 12 have been rejected. Claims 4-10 have been objected and not further treated on the merit as being of improper multiple dependent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CYNTHIA WILDER
PATENT EXAMINER

3/3/2004